AMENDMENTS TO THE DRAWINGS

Applicant submits herewith a replacement drawing sheet for FIGS. 1, 2, and 9. No new matter has been added by way of this amendment.

Applicant has amended FIGS. 1 and 2 to delete reference numbers not described in the specification. Additionally, Applicants' specification refers to "electronic valve reader 901" in the description of FIG. 9. However, the electronic valve reader illustrated by FIG. 9 was inadvertently improperly identified with reference number "900." The attached sheets include a new version of FIG. 9 that replaces the incorrect reference number "900" with the correct reference number "901" for the electronic valve reader.

Attachment: Replacement Sheets (2)

REMARKS

This Amendment is responsive to the Office Action dated October 5, 2006. Applicant has amended claims 1, 2, 3, 6, 8-11, 13, 14, 16, 17, 21, 23-25, and 30. Claims 1-30 are pending.

Claim Objections

In the Office Action, the Examiner objected to claim 10, because in line 2 "the" should be inserted between "while" and "magnetic"; and objected to claim 30 because in line 2 "sensor" should read "sensors." Applicant has amended claims 10 and 30 to correct these typographical errors. Additionally, the Examiner objected to claim 21, because it is a duplicate of claim 11; and objected to claim 25, because it is a duplicate of claim 15. Applicant has amended claims 21 and 25 to recite dependence on claims 16 and 24, respectively, which differentiates claims 21 and 25 from claims 11 and 15. Withdrawal of these objections is requested.

Claim Rejection Under 35 U.S.C. § 112

In the Office Action, the Examiner rejected claims 1-15, 23 and 25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has amended claims 13 and 23 for purposes of clarification.

With respect to claim 1, the Examiner stated that it is unclear from the language of claim 1 whether the valve is positively claimed. Applicant's claim 1 is directed to an electronic magnetic-based indicator tool comprising a processing module for determining a setting for a valve on an implantable flow control device using a determined orientation of a magnetic indicator device. The valve is not a part of the indicator tool. Instead, the processing module of the indicator tool determines a setting for the valve. Therefore, the valve is not positively claimed as an element of the indicator tool.

Applicant submits that claims 1-15, 23 and 25 particularly point out and distinctly claim the subject matter, as required by 35 U.S.C. 112, second paragraph.

Claim Rejection Under 35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 1-3 under 35 U.S.C. 102(b) as being anticipated by Golden et al. (US 5,425,382, herein referred to as Golden); and rejected claims 1, 4-7, 11, 13-14, 26-30 under 35 U.S.C. 102(b) as being anticipated by Haynor et al. (U.S. 6,129,668, herein referred to as Haynor). Applicant respectfully traverses the rejection. The applied references fail to disclose each and every feature of the claimed invention, as required by 35 U.S.C. 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

Golden

Golden fails to teach or suggest an electronic magnetic-based indicator tool comprising a housing having an electronic display, a plurality of magnetic field sensors, the plurality of magnetic field sensors grouped into sets of magnetic field sensors to determine spatial location and orientation of a magnetic indicator device associated with a valve of an implantable flow control device, and a processing module for receiving magnetic data values from the plurality of magnetic field sensors and for determining a setting for the valve on the implantable flow control device using the determined orientation of the magnetic indicator device, as recited by Applicant's amended claim 1.

In support of the rejection of claim 1, the Examiner stated that the device is capable of determining a setting for a valve on an implantable flow control device, because the device determines the orientation of a magnetic device.[1] Golden describes determining a position and orientation of a magnetic device, such as a medical tube or catheter, but fails to disclose or suggest determining a valve orientation setting based on the determined orientation. Golden describes displaying a magnitude signal and optionally displaying a polarity signal. Golden does not disclose or suggest a processing module for determining a setting for a valve on an implantable flow control device using a determined orientation of a magnetic indicator device.

With respect to claim 2, Golden fails to disclose or suggest a processing module that determines the setting of the valve on the implantable flow control device using a determined

[1] Office Action, page 4.

orientation of a reference magnet coupled to the implantable flow control device at a location separate from the magnetic indicator device. Golden does not disclose or suggest determining a setting of a valve on an implantable flow control device and, instead, describes determining a position and orientation of a magnetic device. Additionally, Golden does not disclose or suggest using a determined orientation of a reference magnet to determine a setting of a valve. Golden does not contemplate determining a setting of a valve and fails to disclose or suggest each and every requirement of Applicant's amended claim 2.

Haynor

Like Golden, Haynor also fails to teach or suggest an electronic magnetic-based indicator tool comprising a housing having an electronic display, a plurality of magnetic field sensors, the plurality of magnetic field sensors grouped into sets of magnetic field sensors to determine spatial location and orientation of a magnetic indicator device associated with a valve of an implantable flow control device, and a processing module for receiving magnetic data values from the plurality of magnetic field sensors and for determining a setting for the valve on the implantable flow control device using the determined orientation of the magnetic indicator device, as recited by Applicant's amended claim 1.

In support of the rejection of claim 1, the Examiner stated that the device is capable of determining a setting for a valve on an implantable flow control device. However, Haynor describes determining a location of a medical device, such as a medical tube or device. Haynor fails to disclose or suggest determining a valve setting based on a determined orientation of a magnetic indicator device. Haynor determines the location of a medical tube by sensing the magnetic field produced by a permanent magnet associated with the medical tube.[2] Haynor fails to disclose or suggest determining a valve setting based on the determined orientation of a magnetic indicator device and, therefore, fails to disclose or suggest each and every requirement of claim 1.

With respect to claim 11, Haynor fails to disclose or suggest a removable data storage device containing computer readable data for translating the setting of the valve to a pressure for

[2] Haynor, column 4, lines 43-63.

the implantable flow control device. As described with respect to claim 1, Haynor does not even contemplate determining a valve setting. In support of the rejection of claim 11, the Examiner cited conventional video cassette recorder 170 of Haynor's disclosure as teaching the requirements of claim 11. Conventional video cassette recorder 170 can record images generated by a fluoroscope system and images generated by a detector system and combine the images generated by the detector system with image data generated by conventional techniques.[3] Conventional video cassette recorder 170 is used to combine image data from multiple sources. Convention video cassette recorder 170 does not store data for translating a setting of a valve to a pressure for an implantable flow control device. For at least these reasons, Haynor fails to disclose or suggest the requirements of claim 11.

Haynor fails to disclose or suggest computer readable data corresponding to a particular model of an implantable flow control device for translating a setting of a valve to a pressure for the implantable flow control device, as required by Applicant's amended claim 13. As originally presented, the Examiner read claim 13 as reciting computer readable data corresponding to a particular model of software. Applicant has amended claim 13 for purposes of clarification and asserts that Haynor fails to disclose or suggest computer readable data corresponding to a particular model of an implantable flow control device.

Haynor also fails to disclose or suggest a method comprising placing an electronic magnetic-based indicator tool adjacent to an implantable medical device, the implantable medical device having a magnetic indicator device coupled to a valve used to control operation of the medical device, measuring a magnetic field strength observed by the indicator tool, estimating a portion of the observed magnetic fields caused by an environmental magnetic field, determining an orientation of the magnetic indicator device relative to a known position of the implantable medical device using the observed magnetic field and the estimate for the environmental magnetic field, and indicating a device setting of the implantable medical device, as required by Applicant's independent claim 26.

Haynor fails to disclose or suggest an implantable medical device having a magnetic indicator device coupled to a valve used to control operation of the medical device. Additionally,

[3] Haynor, column 12, lines 42-56.

Haynor describes determining a location of a medical tube or device but does not disclose or suggest indicating a device setting of the implantable medical device. For at least these reasons, Haynor fails to disclose or suggest the requirements of claim 26.

The applied references fail to disclose each and every limitation set forth in claims 1, 11, 13, and 26. Claims 2-7 and 14 are dependent upon claim 1, and claims 27-30 are dependent upon claim 26. These dependent claims are also in condition for allowance. For at least these reasons, the applied references have failed to establish a prima facie case for anticipation of Applicant's claims 1-7, 11, 13-14, 26-30 under 35 U.S.C. 102(b). Withdrawal of this rejection is requested.

Claim Rejection Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 4 and 5 under 35 U.S.C. 103(a) as being unpatentable over Golden; rejected claims 8-10 under 35 U.S.C. 103(a) as being unpatentable over Golden in view of Ito (US 2001/0022350, herein referred to as Ito); rejected claim 15 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Haynor; rejected claims 16-21, and 23-25 under 35 U.S.C. 103(a) as being unpatentable over Haynor in view of Ito; and rejected claims 12 and 21-22 under 35 U.S.C. 103(a) as being unpatentable over Haynor in view of Ito in further view of Drinan et al. (US 2003/0004403, herein referred to as Drinan). Applicant respectfully traverses the rejection. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Initially, Applicant notes that the secondary references provide no teaching that would have overcome the deficiencies of Golden and Haynor with respect to the requirements Applicant's independent claims discussed above. For at least this reason, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 4, 5, 8-10, 12, and 15-25 under 35 U.S.C. § 103(a), and the rejections of each of these claims should be withdrawn. Moreover, the applied references, either alone or in combination, fail to teach or suggest a number of the additional requirements recited in these claims.

Additionally, with respect to independent claim 16, the applied references fail to disclose or suggest a system comprising an implantable medical device comprising a magnetic indicator device associated with a valve of an implantable flow control device to indicate a current setting of the implantable flow control device, an electronic magnetic-based indicator tool comprising a housing having an electronic display, a plurality of magnetic field sensors, the plurality of magnetic field sensors grouped into sets of three magnetic field sensors, and a processing module for receiving magnetic data values from the plurality of magnetic field sensors and for determining a setting for the valve on the implantable flow control device using a determined orientation of the magnetic indicator device coupled to the valve, and an adjustment tool for modifying an orientation of the valve in the implantable flow control device, the adjustment tool comprises a magnetic adjustment component for magnetically coupling to the magnetic indicator device of the flow control device.

In support of the rejection of claim 16, the Examiner acknowledged that Haynor fails to disclose or suggest an adjustment tool comprising a magnetic adjustment component for magnetically coupling to the magnetic indicator device of the flow control device and suggested modifying the Haynor system to include an adjustment tool as taught by Ito. Haynor describes determining a location of a medical device, such as a medical tube or device. However, Haynor does not disclose or suggest determining a setting for a valve on an implantable flow control device using a determined orientation of a magnetic indicator device coupled to the valve. In fact, Haynor does not disclose or suggest determining a setting for a valve whatsoever. Since Haynor does not disclose or suggest determining a setting for a valve, it is unclear why one of ordinary skill in the art would have even considered the teachings of Ito when contemplating the system of Haynor. For at least these reasons, the applied references fail to disclose or suggest the requirements of claim 16.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 4, 5, 8-10, 12, and 15-25 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the clear distinctions identified above between the current claims and the applied prior art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not necessarily admit or acquiesce in any of the rejections or the Examiner's interpretations of the applied references. Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: January 5, 2007

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